OCT - 5 2000

K002857

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY

COMPANY NAME AND CONTACT PERSON

July 28, 2000

Jostra AG
Hechinger Straße 38
72145 Hirrlingen
Germany

Kathyleen Johnson, Sales & Marketing Manager
Phone 888-567-8721
Fax (302) 454 8700

DEVICE NAME

ELS Cannula (M1210-88, M1510-88)

COMMON NAME

Double lumen cannula

CLASSIFICATION NAME

Cardiopulmonary bypass vascular catheter, cannula or tubing (21 CFR – 870.4210)

PREDICATE DEVICE OR LEGALLY MARKETED DEVICE

Kendall Infant ECMO VenoVenous Catheter- Dual Lumen, Kendall Healthcare Products Co. Div. of Tyco Health

DEVICE DESCRIPTION

With the concept of the extracorporeal membrane oxygenation (ECMO) a temporary support technique is available which allows a sufficient oxgenation and CO_2 removal for patients with a cardiac failure and/or lung failure.

Within the scope of ECMO the ELS Cannula is used for the treatment of respiratory insufficiency in infants and newborns. It is intended for venovenous perfusion via the right side of the internal jugular vein.

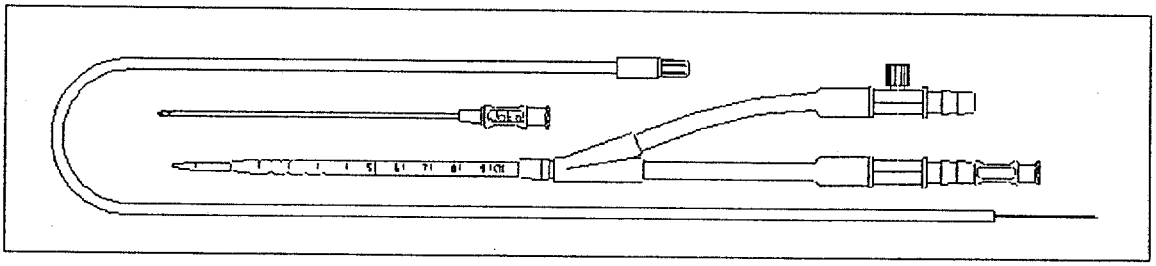
The Jostra ELS Cannula is a double lumen cannula featuring a draining lumen and a perfusion lumen. The cannula is designed to be placed with its tip in the center of the right atrium through the right internal jugular vein with the side holes of the perfusion lumen being placed towards the tricuspid valve.

The venovenous bypass is one of the standard procedures used in ECMO. With this procedure a single cannula is introduced in the jugular vein and used for taking of venous blood and the recirculation of oxygenated blood. The double lumen of the ELS Cannula allows a separation of the venous and the arterial blood flow. The cannula is mostly used percutaneously placed in the internal jugular vein. Therefore puncture needle, guide wire and vascular dilator are provided with the ELS Cannula in a kit.

The ELS Cannula kit consists of the following components:

1. ELS Cannula
2. Vascular dilator
3. Guide wire
4. Puncture needle

Drawing of the kit including the ELS Cannula M 1510:



Design specifications:

The ELS Cannula is a polyurethane catheter with an outside diameter (OD) of 12 Fr or 15 Fr. The perfusion lumen has 4 lateral openings and the draining lumen comes with central hole and 4 lateral openings. The following product variations are available:

Article number	Outer diameter	Tip length	Connection
M 1210-88	12 Fr (4.0 mm)	100 mm	¼"
M 1510-88	15 Fr (5.0 mm)	100 mm	¼"

INTENDED USE

The ELS Cannula is intended to be used as a single cannula for both venous drainage and reinfusion of blood in the right atrium, via the internal jugular vein, during ECMO procedures.

Technical Specifications

Name of the Product	ELS-Cannula (kit) (Jostra)		Kendall Dual Lumen ECMO Catheter (Kendall Healthcare Products Co. Div. of Tyco Health
Parameter			
510(k) number	not assigned		K895352
Specifications:			
Model number:	M1210-88	M1510-88	5914
Recommended blood flow rate: arterial venous	max. 0.5 liters / min. max. 1.0 liters / min.		max. 0.5 liters / min (max. at 100 cm of water, vacuum)
Catheter Size (OD)	12 Fr	15 Fr	14 Fr
Connector Size	3/16 in / ¼ in		3/16 in / ¼ in
Catheter Length	10 cm		10 cm
Material	radiopaque polyurethane (PUR)		radiopaque polyurethane (PUR)
Use	Single-use device		Single-use device

SAFETY TESTING

Biocompatibility:

Biocompatibility testing of the ELS Cannula was performed in accordance with the FDA Blue Book Memorandum - #G95-1 and Biological Evaluation of Medical Devices Guidance – International Standard ISO 10993-1, and in accordance with United States Pharmacopeia – XXIII.

Based on the results of the biocompatibility testing performed, ELS Cannula was determined to be biocompatible and nontoxic and, therefore, safe for its intended use.

Sterility:

Sterilization of the ELS Cannula has been validated to assure a sterility assurance level (SAL) of 10^{-6}.

EtO sterilized ELS Cannula are according to Federal Register , Vol. 43, No. 122 – Friday, June 23, 1978.

EtO Residuals:

The ELS Cannula meets the limits for residual concentrations of ethylene oxide (<25 ppm), ethylene chlorohydrin (<25 ppm), and ethylene glycol (< 250 ppm) as published in Federal Register , Vol. 43, No. 122 – Friday, June 23, 1978.

Pyrogens:

Routine Pyrogen Testing is performed using the Limulus Amebocyte Lysate (LAL) method. Product testing and release criteria (less than 20 EU/ml) is in accordance to the December 1987 Guideline issued by the Food and Drug Administration, office of Compliance („Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices").

EFFECTIVENESS TESTING

Effectiveness of the ELS Cannula was determined by evaluating its operational characteristics.

Performance testing showed that the ELS Cannula is effective and meets all functional requirements of a double lumen cannula.

Conclusion

Performance, function, sterility and biocompatibility testing demonstrated ELS Cannula, when compared to the Predicate device (Kendall Double Lumen Catheter), does not significantly affect safety and effectiveness and thus is substantially equivalent to the Kendall Double Lumen Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 5 2000

JOSTRA® AG
c/o Ms. Kathleen Johnson
Sales and Marketing Manager
2035 Sunset Lake Road
Newark, DE 19702

Re: K002857
Trade Name: ELS CANNULA, Model M1210-88, M1510-88
Regulatory Class: II (two)
Product Code: DWF
Dated: July 28, 2000
Received: September 13, 2000

Dear Ms. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K002857

Device Name: ELS Cannula

Indications for Use ELS Cannula

The ELS Cannula is intended to be used as a single cannula for both venous drainage and reinfusion of blood in the rightatrium, via the internal jugular vein, during neonatal ECMO procedures

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Concurrence of CDRH, Office of Device Evaluation(ODE)

(Optional Format3-10-98)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K002857